UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF COMPLIANCE

FIFRA GLP INSPECTION REPORT

Microchem Laboratory, LLC (formerly Antimicrobial Test Laboratories)
Round Rock, Texas

November 30 – December 1, 2016

Daniel M. Myers

OFFICE OF COMPLIANCE, GLP PROGRAM
Denver, Colorado

REPORT OF A GLP COMPLIANCE INSPECTION CONDUCTED PURSUANT TO THE FIFRA REGULATIONS

LABORATORY:	Microchem Laboratory, LLC (formerly Antimicrobial Test Laboratories) 1304 W. Industrial Blvd. Round Rock, TX 78681
INVESTIGATION ID:	20171088908
RESPONSIBLE OFFICIAL:	Dr. Benjamin Tanner President and CEO Phone: (512) 310-8378
DATE OF INSPECTION:	November 30 – December 1, 2016

TABLE OF CONTENTS

SUMMARY

A FIFRA GLP inspection was conducted at Microchem Laboratory, LLC (formerly Antimicrobial Test Laboratories), in Round Rock, Texas, on November 30 – December 1, 2016. This inspection was requested by EPA's Office of Pesticide Programs. Three study audits were accomplished in addition to a GLP compliance review. Findings for the compliance review and the study audits are summarized below.

- The laboratory agrees to conduct the viral titer calculation in a way that is consistent with EPA's requirements using the Spearman – Karber method for calculations.

- For one study, the study report shows data for the "Neutralization Effectiveness Control" at the 10^{-4} dilution. There is no raw data to support this.

I. INTRODUCTION

A routine FIFRA GLP inspection was conducted at Microchem Laboratory, LLC (formerly Antimicrobial Test Laboratories (ATL)) on November 30 – December 1, 2016, at the request of the U.S. EPA Office of Compliance (OC) and Office of Pesticide Programs. Microchem Laboratory, LLC / ATL officials were notified of the pending inspection via letter [Exhibit 1] from Francisca Liem, Director of OC's GLP Program. The letter identified the inspection team, the studies to be audited and the data and records to be made available. The letter was addressed to Dr. Benjamin Tanner, President and CEO of Microchem Laboratory, LLC / ATL.

In the weeks preceding the site inspection, Dr. Tanner, was contacted by the lead inspector, Daniel M. Myers from OC's GLP Program, via telephone and e-mail to discuss the upcoming inspection logistics. Mr. Myers explained that he would conduct a FIFRA GLP and Books and Records inspection involving three study audits and a GLP compliance review.

II. OPENING CONFERENCE

An opening conference was held beginning at approximately 9:00 a.m. on November 30, 2017. The inspection and data audits were conducted solely by Mr. Daniel M. Myers, Chemist, from EPA's GLP Program.

Official credentials were presented to facility officials upon entry. A FIFRA Notice of Inspection [Exhibit 2] was presented to and signed by Dr. Tanner. Mr. Myers informed facility employees that the inspection was requested by EPA's Office of Pesticide Programs to evaluate the facility's use of the Spearman-Karber calculation.

The opening conference consisted of Mr. Myers, Dr. Tanner and Travis Chesser, Quality Assurance Specialist. Dr. Tanner gave a verbal summary of the facility's history including the scope of their operations and the extent of FIFRA related work. Additional details for the conduct of the inspection were discussed and an inspection schedule was agreed upon.

III. HISTORY OF THE FACILITY

Antimicrobial Test Laboratories was founded in 2006 by Dr. Benjamin Tanner, who formerly worked with University of Arizona and other companies before starting ATL in California. In 2007 the company moved to Austin Texas, and in 2011, moved to its current location in Round Rock, Texas. In 2014, Dr. Tanner purchased Microchem Laboratory from the Dallas area and in December of 2015 changed the name of the larger organization to Microchem Laboratory, LLC.

Microchem Laboratory, LLC is a microbiology laboratory that conducts antimicrobial treated article testing, preservative challenging testing, virology, discovery and screening. Dr. Tanner estimates that approximately 20% of their work is regulated by the GLP standards.

Microchem Laboratory, LLC has grown to its current size of 31 employees and occupies approximately 15000ft^2 of office and laboratory space located a few miles north of Austin, TX.

More information can be found at www.MicrochemLab.com

IV. EXIT CONFERENCE

The exit conference was held on Thursday, December 1, 2016, by Mr. Myers to review findings and recommendations of the FIFRA GLP inspection and data audits. Microchem employees present at the closing conference were Dr. Tanner and Mr. Chesser. An Inspection Observations form [Exhibit 3] was completed, signed and copied for Dr. Tanner, providing written indication of findings discussed in the closing conference. A FIFRA Receipt for Samples [Exhibit 4] was provided to Dr. Tanner for all documents obtained during the inspection.

V. EXHIBITS

Exhibit 1	Notification Letter (3 pages)
Exhibit 2	FIFRA Notice of Inspection
Exhibit 3	Inspection Observations Form
Exhibit 4	FIFRA Receipt for Samples

VI. SIGNATURE:

Inspector: Name: Daniel M. Myers
Affiliation: EPA, Office of Compliance, GLP Program

Daniel M. Myers — 1/6/2017
Daniel M. Myers — Date

Exhibit 1

Letter of Notification (3 pages)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

NOV 17 2016

OFFICE OF
ENFORCEMENT AND
COMPLIANCE ASSURANCE

SCAN AND EMAIL
CONFIRMATION OF RECEIPT REQUESTED

Dr. Benjamin Tanner
Antimicrobial Test Laboratories / Microchem Laboratory
1304 W. Industrial Blvd.
Round Rock, TX 78681

Dear Dr. Tanner:

This is to inform you that the Environmental Protection Agency (EPA) will conduct a Good Laboratory Practice (GLP) Inspection at your facility under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

The inspection will be conducted during the week of November 28, 2016. The inspection will be led by Daniel Myers. The inspection team will review your facility's compliance status with the EPA FIFRA GLP regulations at 40 Code of Federal Regulations (CFR) Part 160 and will audit those aspects of the studies listed in Attachment I performed by Antimicrobial Test Laboratories / Microchem Laboratory.

In addition, the inspection team will choose one or more completed or ongoing studies from your Master Schedule for audit.

The purpose of study audits is to validate data in final reports which have been presented to the EPA in support of a registration or marketing petition under FIFRA.

The purpose of the compliance review is to determine that the GLP regulations of FIFRA are being observed in your testing facility's current procedures and practices for pertinent studies being conducted.

Please note that under the FIFRA GLP regulations at 40 CFR 160.15(b) EPA will not consider reliable for purposes of supporting a FIFRA application for a research or marketing permit any data developed by a testing facility that refuses to permit inspection.

To successfully conduct our inspection, we request that the following matters be addressed prior to our arrival at Antimicrobial Test Laboratories / Microchem Laboratory.

Please make available suitable space for the team. Please have available and in good order all original data needed to verify the final report of each study, along with full copies of the protocol (including protocol amendments) and all reports submitted by your facility to the study sponsors. All current personnel who were associated with these studies should be available for discussion with members of the team as necessary. The inspection team will need for review copies of all Standard Operating Procedures (SOP) documents in use at the time of study.

We will require very specific information at your facility regarding the test substance. This includes, but is not necessarily limited to, the source and lot number, analysis for purity and identification, record of receipt, and storage, usage data, test substance inventory logs and custodial procedures for each test substance. Records and data should also be available to document the synthesis, radiochemical purity and specific activity of any radio labeled test or reference substance used at your facility for the conduct of the studies being audited.

In addition, please obtain a statement from the sponsor indicating the origin of the test substance, namely, if it was sampled from a batch for contemporary commercial use or was synthesized or manufactured for the specific study for which the raw data are being audited. In either case, the statement should include chemistry data, i.e., all data to prove the identity and purity of the test substance, the identity of any and all impurities detected by sponsor or manufacturer, and data to prove storage stability of the test substance during the lifetime of the study.

If there are any questions arising from this notice please feel free to call me directly. Under ordinary conditions the dates selected for the inspection will not be changed. I may be reached during regular hours at (202) 564-2365.

Sincerely,

Francisca E. Liem, Director
Good Laboratory Practice Program

Enclosure

Attachment I

STUDY AUDITS

Test Substance	Study	Lab Project No.	MRID No.
VO RTU LCL	GLP Evaluation of the Virucidal Efficacy of VO RTU LCL on Inanimate, Nonporous Environmental Surfaces	GLP1346	49852905
Vital Oxide - VO RTU LCL	GLP Evaluation of the Virucidal Efficacy of Vital Oxide - VO RTU LCL on Inanimate, Nonporous Environmental Surfaces	GLP1357	49852906
NF-El-EF	AOAC Germicidal and Detergent Sanitizing Action of Disinfectants	GLP1338	49972805

Exhibit 2

FIFRA Notice of Inspection

U.S. ENVIRONMENTAL PROTECTION AGENCY

GOOD LABORATORY PRACTICE

NOTICE OF INSPECTION

ADDRESS (*EPA Office*)
Office of Compliance
Bldg 25, Box 25227
Denver, CO 80225

DATE: 11/30/2016

HOUR: 9:00 AM / PM

FIRM NAME: Antimicrobial Test Laboratories / Microchem Laboratory	FIRM ADDRESS (*NUMBER, STREET, CITY, STATE AND ZIP CODE*): 1304 W. Industrial Blvd, Round Rock, TX 78681 11/22/16
NAME OF OWNER OR AGENT IN CHARGE: Benjamin Tarnel	
SIGNATURE OF OWNER OR AGENT IN CHARGE (***SIGNATURE GRANTS CONSENT TO INSPECTION***): B T	SIGNATURE OF EPA EMPLOYEE: Daniel Myers Daniel Myers
TITLE: CEO	TITLE: Compliance Officer

REASON FOR INSPECTION:

☒ FOR THE PURPOSE OF PERFORMING AN INSPECTION PURSUANT TO THE GOOD LABORATORY PRACTICE STANDARDS SPECIFIED IN SECTION 40 CFR PART 160

☒ FOR THE PURPOSE OF INSPECTING AND OBTAINING COPIES OF THOSE RECORDS SPECIFIED IN THE FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT, SECTIONS 8 and 12(a)(2)(B), AND IN SECTION 40 CFR PART 169.

☐

☐

VIOLATION SUSPECTED: OPP Requested inspection

Exhibit 3

Inspection Observations Form

EPA INSPECTION OBSERVATIONS

ADDRESS/PHONE (EPA OFFICE)
Box 25227, Bldg. 25
Denver Federal Center
Denver, CO 80225

DATE 12/1/2016

PRINTED NAME OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Benjamin Tanner

INVESTIGATION ID NUMBER
2017088908

FIRM NAME AND ADDRESS:
Antimicrobial Test Laboratories / Microchem Laboratory
1304 W. Industrial Blvd.
Round Rock, TX 78681

FACILITY INSPECTED ADDRESS
Same.

DURING AN INSPECTION / AUDIT OF YOUR FACILITY, THE FOLLOWING POTENTIAL VIOLATIONS WERE OBSERVED BY AGENCY INSPECTORS:

For a FIFRA GLP inspection and audit of Studies GLP 1346, GLP1357 and GLP 1338.

- The laboratory agrees to conduct the viral titer calculation in a way that is consistent with EPA's interpretation of the Spearman-Karber method for calculations.
- For study GLP 1357, the study report shows data for the "Neutralization Effectiveness Control" at the 10^{-4} dilution. There is NO raw data to support this. The report has been amended. This amendment also shows the updated Spearman-Karber calculations.

D.M. 12/1/2016

NOTE: This form provides only preliminary determinations by Agency inspectors. Final determinations concerning the number, nature and extent of violations will be made following enforcement review of the inspection report.

ACKNOWLEDGMENT
THE UNDERSIGNED ACKNOWLEDGES RECEIPT OF A COPY OF THIS INFORMATION

SIGNATURE

TITLE CEO

PREPARED BY: Daniel Myers

TITLE Chemist / Inspector

EPA 3540-38 (12-95)

Exhibit 4

FIFRA Receipt for Samples

U.S. ENVIRONMENTAL PROTECTION AGENCY

RECEIPT FOR SAMPLES

ADDRESS (*EPA Regional Office*)	Office of Compliance Bldg 25, Box 25227 Denver, CO 80225
DATE	12/1/2016

NAME OF INDIVIDUAL	TITLE
[illegible]	[illegible]
FIRM NAME	**ADDRESS** (*Street, City, State and Zip Code*)
Antimicrobial Test Laboratories/ Microchem Laboratory	1304 W Industrial Blvd Round Rock, TX 78681

SAMPLE NUMBERS

SAMPLES COLLECTED (*Describe fully, List Registration, Lot, Batch, Model, Serial Numbers and other positive identifications.*)

The following samples were collected by the U.S. Environmental Protection Agency and receipt is hereby acknowledged persuant to Section 9.(a) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (7 U.S.C. 136 g). This section is quoted on the reverse of this form.

1) [illegible] (1 page)
2) Neutralization Chart (3 pages)
3) Spearman Karber Calculation information (8 pages)
4) Study GLP 1357 raw data page showing Neutralization Effectiveness Control (2 pages)
5) Protocol P1704 (15 pages)
6) [illegible] Titer calculation page for study GLP1581 (2 pages)
7) Letter to EPA and SOPs [illegible] and 0073 (Test Facility operation) (25 pages)
8) Amended Report for study GLP 1357 (38 pages)
9) [illegible]

ACKNOWLEDGMENT OF PRODUCER/REGISTRANT

The undersigned acknowledges that the samples shown above were obtained from pesticides or devices that were packaged, labeled, and released for shipment.

SIGNATURE (*Owner, Operator, or Agent*)	TITLE (*Owner, Operator or Agent*)

☐ DUPLICATE SAMPLES REQUESTED AND PROVIDED ☐ DUPLICATE SAMPLES NOT REQUESTED N/A

SAMPLES WERE ☐ PURCHASED ☐ BORROWED

AMOUNT PAID FOR SAMPLES $ ☐ CASH ☐ VOUCHER ☐ TO BE BILLED

NAME OF COLLECTOR (*Print or type*)	TITLE OF COLLECTOR	SIGNATURE OF COLLECTOR
Daniel Myers	Compliance Officer	[signature]

EIR COPY